REMARKS

Claims 1-17 are pending in the application. Support for new claim 15 appears, e.g., on page 7, line 1; support for new claim 16 appears on, e.g., page 7, line 4; support for new claim 17 is available on, e.g., page 10, line 5. No new matter has been added.

A Petition to Accept an Unintentionally Delayed Benefit Claim under 35 U.S.C. § 119 accompanies this Response along with the appropriate fee.

Rejections under 35 USC § 102(b)

The Examiner rejected claims 1 and 4 over U.S. Patent 3,146,169 ("Spence"), stating that Spence teaches a tablet with an inert portion that surrounds an active portion; an active portion comprising a core; and an inert portion comprising barium sulphate or aluminium silicate. Applicant traverses the rejection.

Claim 1, from which depends claim 4, requires a core containing an active substance with a compression coating surrounding the core. Spence does not teach a tablet that has a core with these features. On the contrary, Spence describes a tablet in which a medicated portion covers part, but not all, of the surface of the inert portion (See Col. 1, lines 26-27, and lines 49-53; Col. 3, lines 22-26; [Emphasis in Original]):

> [A] tablet comprising a medicated portion and a non-medicated inert portion . . . which covers part but not all of the surface of the inert portion ...
> In Figures I and II there is shown a tablet consisting of a medicated portion **1**, an inert portion **2** which around the medicated portion **1** and is provided with a hole **3**, which extends into the medicated portion **1** and through which the medicament in the portion **1** is slowly released
> . . . .
> Suitable substances from which material of the inert portion may be made are . . . barium sulphate . . . aluminium silicate . . . .

Col. 1, lines 33-36 and Figure IV, the portions of Spence relied on by the examiner for the rejection, also fail to teach this feature of the invention. The tablet

structure referenced in Figure IV includes a hole 3 that extends into a medicament portion and into which a medicament is released after being swallowed.

Claim 1 also requires that the active substance containing core comprise a colorant excipient, such as aluminium silicate, or an excipient that is opaque to x-rays. This feature is not taught in Spence. This reference instead teaches that the non-medicated inert portion surrounding the medicated portion contains the barium sulphate or aluminium silicate. But Spence does not teach a tablet where the barium sulphate or aluminium silicate is in the core-containing the active substance, nor does it teach an excipient that is opaque to x-rays such that when the tablet is exposed to penetrating radiation the core is contrasted with the coating and is visible through the coating.

Spence does not teach every element of claims 1 and 4 and therefore does not anticipate the invention now claimed. Applicants request reconsideration and withdrawal of the rejection.

Rejections under 35 USC § 103(a)

The Examiner rejected claims 1 and 4-6 as obvious over Spence. The rejection is traversed.

The examiner must first establish a *prima facie* case of obviousness. This requires that "either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *See* MPEP § 706.02(j) citing *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Knowledge of the disclosure provided by the instant application must be put aside when determining whether the claimed invention would have been obvious. *See* MPEP § 2142. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one ordinary skill in the art. *See* MPEP § 2143.01, citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 416, 82 USPQ2d 1385, 1396 (2007). Furthermore, a statement that modifications of the prior art to meet the claimed

invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. See MPEP §2143.01, citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

It is clear, that at the very least, the Office Action fails to properly consider the distinct nature of the tablets specified in claim 1. MPEP § 2143.03 requires that all claim limitations must be considered for an obviousness rejection:

> "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending there from is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).[1]

Claim 1, from which the remaining claims subject to the rejection depend, is drawn to a tablet with a core containing an active substance and which is surrounded by a compression coating.

This feature of claim 1 is not described or suggested by Spence. Unlike in Spence, where the aluminium silicate is within the outer inert – non-medicated – portion of the tablet, the excipients in the claimed tablet are part of the medicated inner core. Thus, the core as defined in the claim 1 is distinct from the core the Examiner identifies in Spence.

In contrast, Spence teaches a multi-layered tablet where the medicated portion is surrounded by an inert portion and two outer layers. The tablet in Spence is designed for slowly releasing medicament as the tablet passes through the gastro-intestinal tract of the patient, with the goal of providing continuous administration of the medicament over a considerable amount of time. (*See* Spence at col. 1, lines 18-21.) Spence achieves this objective by preparing a tablet with a medicated portion and a separate non-medicated

[1] MPEP § 2143.03

inert portion, which partially covers the medicated portion. This feature is excluded by the present claims, which require a compression coating surrounding a core.

In Spence, the **outer inert portion** of the tablet comprises calcium silicate or aluminium silicate. (*See* claims 1 and 5-6; [Emphasis added].) The inert non-medicated portion, in contrast, is made up of material that is substantially insoluble, indigestible, and unabsorbable in gastro-intestinal tract and substantially impermeable to the medicament, thus allowing only a portion of the medicated portion to be exposed to the fluids on the gastro-intestinal tract. (*See* col. 1, lines 37-40, and col. 2, lines 8-10.) The additional outer layers of the tablet in Spence protect the tablet from further damage. (*See* col. 3, lines 35-40.)

The current invention also solves a problem not recognized by Spence. The presently claimed invention is based on the Applicants insight that imprecision in the positioning of a tablet core during manufacturing can result in a broken core and core-material contaminating the coating. By adding colorants in the core, the position of the core can be easily located, allowing examination of the core in a coating. (*See* page 2, lines 12-28 of the specification). No teaching of this feature, explicit or otherwise, is present in Spence.

Because Spence does not teach or suggest a tablet where the excipients are part of the medicated inner core, the reference does not render the current claimed invention obvious. Applicants request reconsideration and withdrawal of the rejection.

Rejections over Spence in view of Thurn-Müller

The Examiner rejected claims 2, 12, and 13 as obvious over Spence, further in view of Thurn-Müller *et al.*, (U.S. Patent 5,310,578, issued on May 10, 1994) The rejection is traversed.

Claims 2, 12, and 13 depend from claim 1 and are non-obvious over Spence for the reasons discussed above.

Thurn-Müller does not remedy the deficiency in Spence. According to the Examiner, Thurn-Müller teaches that "red iron oxide, aluminium silicate and calcium

silicate are well known examples of pigments" (*see* Office Action, p. 7, ¶ 5). But there is no teaching, suggestion, or motivation in this reference for preparing a tablet where the excipients are part of the medicated inner core. This reference, therefore, fails to overcome the deficiencies of Spence. Applicants request reconsideration and withdrawal of the rejection.

Rejections over Spence in view of Guglielmotti

The Examiner rejected claims 7, 8, and 14 as obvious over Spence, further in view of Guglielmotti *et al.*, (U.S. Patent 6,020,356, issued on February 1, 2000). The rejection is traversed.

Claims 7, 8, and 14 depend from claim 1 and are non-obvious over Spence for the reasons discussed above. Guglielmotti is cited for teaching the treatment of several conditions with bindarit and an immunosuppressant such as prednisone. However, it does not overcome the deficiencies of Spence. While Guglielmotti is cited for teaching a composition comprising the medicament and any excipient, this reference does not offer a reason to refrain from adding to the non-medicated inert coating as taught in Spence. Indeed, by following Spence and Guglielmotti one would add colorant in both the medicated core and non-medicated coating of the current invention, thus preparing a tablet lacking the necessary advantage of the colorant as disclosed in the current application (*see* page 2, lines 26-28 of the specification). Thus, the combination of Spence and Guglielmotti effectively would result in a different tablet and to this extent teaches away from the tablet claimed in this application.

Applicants submit that the application is in condition for allowance and request an action for same. A Petition for One-Month Extension of Time accompanies this Response, along with the appropriate fee. Please charge any additional fee, or credit any overpayment of same, to Deposit Account No. 50-0311, Attorney Reference No. **28069-618N01US**.

Respectfully submitted,

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